

### **REMARKS/ARGUMENTS**

In this Amendment, claims 64, 87-92, 98-110, 114 and 115 are currently amended; claims 58, 60-63, 65-70, 73, 75-77, 81-84, 86, 93, 95, 111-113 and 116-121 were previously presented; and claims 1-57, 59, 71, 72, 74, 78-80, 85, 94, 96 and 97 are canceled without prejudice or disclaimer. Claims 122-143 are newly presented. It is submitted that no new matter has been added by virtue of the amended and new claims, which are supported by the original and prior claims and by the disclosure of the application as originally filed. Accordingly, the currently pending claims are now claims 58, 60-70, 73, 75-77, 81-84, 86-93, 95 and 98-143.

#### **Support for the amended and new claims**

Support for the amendments to claims 64, 87, 89, 100, 101, 105-110 and 114 is found in the instant specification on page 9, lines 2-3; on page 13, lines 1-6; and on page 16, lines 21-23 of the instant specification. It is respectfully submitted that the term "chemical reaction" is clearly defined and explained in the disclosure (*See, e.g.*, page 9, lines 11-13) such that the currently amended claims would be clearly understood by those having skill in the pertinent art, in view of the disclosure of the specification combined with routine knowledge of those having skill in the art. Support for new claims 122-143 is found in the as-filed specification and in the prior claims.

#### **Election/Restriction**

The Examiner has asserted that the application contains claims directed to thirty-five (i.e., i-xxxv) species of the generic invention defined by claims 87, 107, 108, 109, 110 and 114.

Applicants respectfully traverse this rejection.

The currently amended claims are directed to methods of preparing a composition comprising a biologically active agent and one or more carrier starting substances from which the biologically active agent is releasable, wherein the biologically active agent is saturated to a first degree in the one or more starting carrier substances, and wherein, by practice of the

method, a carrier matrix is produced such that the biologically active agent is saturated in the carrier matrix to a second degree that is higher than the first degree of saturation of the biologically active agent in the starting carrier substances and such that the biologically active agent does not precipitate in the matrix.

The claims have been currently amended so as to remove recitations of alternative language that the Examiner has alleged to be separate species.

The Examiner has considered as separate species a process in which a biologically active agent is dissolved in a carrier starting substance and a process in which a biologically active agent is dispersed in a carrier starting substance. Applicants respectfully disagree that different species are represented or that restriction is warranted. With specific regard to amended and new independent claims 87, 107, 108, 109, 110, 114, 122 and 143, it is submitted that whether a biologically active agent is dissolved or dispersed in one or more carrier starting substances does not constitute distinct species of the claimed methods. Dissolving or dispersing a biologically active agent in one or more carrier starting substances as a step in the claimed methods refers to technical means by which the biologically active agent may be contained in the carrier starting substance(s). A search of the art should not be considered to be unduly burdensome whether or not a biologically active agent is dissolved or dispersed in a carrier substance. These terms do not constitute a separate status in the art and do not necessitate a different field of search. Thus, there is no proper basis for restricting these terms into distinct species.

Additionally, the Examiner has considered as separate species a process which includes the formation of a covalent bond and a process which includes the cleavage of a covalent bond. Applicants respectfully disagree that in the claims as currently presented different species are represented or that restriction is warranted. It is submitted that the currently amended claims obviate a species restriction between forming or cleaving a covalent bond. The formation or cleavage of covalent bonds represents an art-recognized definition of the term "chemical reaction or operation" as recited in the currently amended claims. The instant specification plainly provides the definition of this term as part of the instant disclosure (*See, e.g.*, page 9, lines 11-21 of the as-filed specification).

That a chemical reaction or operation involves forming or cleaving covalent bonds is readily understood and appreciated by those having routine skill in the relevant art. For example, one having skill in the pertinent art would clearly understand the distinction between the term “chemical reaction” and the term “physical reaction”, as explained in Applicants’ March 18, 2005 amendment and response, of record. Thus, the recitation of chemical reaction in the currently amended claims is readily supported by the disclosure of the specification combined with knowledge of those having skill in the art. Accordingly, the claims as currently amended moot a species election between forming or cleaving a covalent bond. It is submitted that the term “chemical reaction” is clearly described in Applicants’ original disclosure and is well understood by those having skill in the art. Consequently, the term is clear in the context of the disclosure of the application combined with the knowledge of those skilled in the art, thus obviating a species restriction as alleged by the Examiner.

The Examiner has considered as separate species a process which includes one carrier starting substance and a process which includes a mixture of two or more different carrier starting substances. Applicants respectfully disagree that different species are represented or that restriction is warranted. Furthermore, the currently amended claims moot a species election between a carrier starting substance and a mixture of two or more different carrier starting substances. As currently amended, Applicants’ claims recite “one or more carrier starting substances”. The teaching of the specification clearly describes and exemplifies that more than one carrier starting substance may be used in the present invention, for example, to allow for the formation of co-polymers and higher polymers (*See, e.g.*, page 12, lines 23-26 and page 16, lines 22-23 of the instant specification). It is thus submitted that the term “one or more carrier starting substances” in the context of the currently amended claims does not constitute multiple species and does not place an undue burden on the Examiner for searching purposes. The term in the currently amended claims should be uniformly classified and the field of search should be the same.

Applicants respectfully assert that in view of the currently amended claims and the foregoing explanation, the present claims reflect a unity of invention and form a single general inventive concept. Thus, it is submitted that the currently amended claims obviate the

designation of separate species (i)-(xxxiii) as set forth in the 01/06/2006 USPTO Communication.

With specific regard to species xxxiv and xxxv related to claim 110 as mentioned by the Examiner on pages 9-10 of the 01/06/2006 Communication, the Examiner states that “initiating a chemical” reaction appears to be new matter that is not supported by the specification as originally filed. Applicants respectfully disagree that the cited phrase is new matter. Indeed, support for this phrase is found in the originally filed specification on page 10, lines 12-13, *et seq.*, where it is disclosed that “... chemical operation(s) is (are) initiated either:” in the presence or the absence of a biologically active agent. Accordingly, the Examiner’s assertion of new matter should be withdrawn.

Applicants respectfully submit that the present claims describe a unified invention that does not represent thirty-five distinct species as set forth by the Examiner. Notwithstanding, to provide a complete response to the USPTO Communication and in accordance with 37 C.F.R. § 1.143, Applicants elect the following species as alleged by the Examiner:

1. election from alternatives set forth on pages 2-9 of the USPTO communication: **applicants elect species i**, directed to a process of preparing a biologically active composition, the process comprises providing a carrier starting substance, dissolving biologically active agent in the carrier starting substance, and subjecting the carrier starting substance to a chemical reaction over a period of time to form a covalent bond; and wherein the chemical reaction is initiated in the presence of the biological agent. However, it should be noted that the claims have been amended to recite one or more carrier starting substances.
2. chemical reaction election: **applicants elect polymerization.**
3. carrier starting substance election: **see below.**
4. one or more carrier starting substances election: **applicants elect acid and alcohol** (*See, e.g.*, page 13, lines 1-6 of the instant specification)
5. biologically active agent election: **applicants elect antifungal agents**

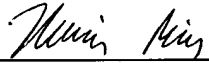
Applicants respectfully submit that the presently amended claims overcome the species restriction/election as set forth by the Examiner. It is further submitted that, at the most, whether the chemical reaction is initiated in the presence or the absence of a biologically active agent may be considered to describe different embodiments of Applicants' claimed invention; however, a search of the relevant art in this regard should not place an undue burden on the Examiner and should not require restriction. In view of all of the foregoing, reconsideration and withdrawal of the restriction requirement is thus respectfully requested.

**CONCLUSION**

Applicants respectfully submit that the application is now in condition for allowance. An action progressing this application to issue is courteously urged. Should any additional fees be deemed to be properly assessable in this application for the timely consideration of this amendment and response, or during the pendency of this application, the Commissioner is hereby authorized to charge any such additional fee(s), or to credit any overpayment, to Deposit Account No. **50-0311**, Reference no. **28069-558 NATL**, Customer Number: **30623**.

Respectfully submitted,  
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY  
AND POPEO, P.C.

Date: July 6, 2006

By:   
Naomi S. Biswas  
Registration No. 38,384

Correspondence Address:  
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY  
AND POPEO, P.C.  
One Financial Center  
Boston, MA 02111  
Telephone: (617) 542-6000  
Facsimile: (617) 542-2241  
Direct Tel.: (617) 348-4401

Express Mail Label No.: EV460368734 US